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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/083,682
Filing Date: October 24, 2001
Appellant(s): WOLFFE ET AL.

Dahna S. Pasternak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/1/2005 and the amended appeal brief filed 10/11/2005 appealing from the Office action mailed 3/31/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner:

The rejection of claims 66-71 and 125-128 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement contained in the final rejection is hereby withdrawn in view of appellant's arguments in the brief.

(7) Claims Appendix

The copy of the appealed claims contained in the Claims Appendix to the brief is correct.

(8) Evidence Relied Upon

Clontech Catalog (1998-1999), pages 177-183, Clontech Laboratories, Inc.

(9) Grounds of Rejection

The following ground of rejection is applicable to the appealed claims:

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66-71 and 125-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Clontech Laboratories (Clontech Catalog, 1998-1999, pages 177-183, Clontech Laboratories, Inc., Palo Alto, California).

The claims are drawn to a polynucleotide or a library comprising the polynucleotides. Each member of the library comprises an insert and a vector, and the insert sequence consists essentially of accessible regions of cellular chromatin.

The claims, as currently written, are apparently product-by-process claims.

The court in *In re Thorpe 777 F.2d 695, 698, 227 USPQ 964,966 (Fed. Cir. 1985)* holds:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Clontech Catalog discloses multiple genomic libraries made from cellular chromatin of different organisms using different vector systems. See pages 177-183, especially the table on pages 182-183. These genomic libraries are made by a method involving digesting genomic DNA, which is from cellular chromatin, of the different organisms with restriction enzymes, Sau3AI and MboI, which are four cutters and are known in the art to digest the genomes with high frequency, and cloning the digested fragments in different vector systems. See page 177. Given that Sau3AI and MboI are restriction enzymes having recognition sites that occur frequently in the genome, it would be readily apparent to one of skill in the art that the libraries produced by such a method inherently comprise clones that either have an insert that consists entirely of polynucleotide sequence from regions of cellular chromatin that are accessible to

reagents such as nuclease and restriction enzymes, as recited in claims 125-128, or have an insert that comprises polynucleotide sequence from the accessible region and sequence from the inaccessible region in the same insert.

Due to the use of transitional phrase "consisting essentially of" in claim 66, it is interpreted that the claimed polynucleotide, i.e. the insert, can include sequence from accessible region and sequence other than the accessible region. Thus, the libraries disclosed by Clontech and certain clones contained therein are the same as the polynucleotides or library thereof in the instant product-by-process claims.

With regard to claim 68, some of the libraries by Clontech comprise polynucleotides from cells at a particular stage of the development, such as from mouse of ages 9-11 weeks, and adult. With regard to claim 69, some of the libraries by Clontech comprise polynucleotides from a particular tissue, such as mouse kidney or mouse liver. With regard to claims 70-71, some of the libraries by Clontech comprise polynucleotides from healthy, such as normal muscle of Xenopus laevis, or diseased cells, such as human Hela S3 cells (from ATCC#CCL2.2, see page 182), which are diseased (cancer) cells and infected with viruses (See page 1 of 3 of the printout of ATCC catalog from ATCC's website). See the listing of genomic libraries on pages 182-183.

(10) Response to Arguments

Claims 66-71 and 125-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Clontech Laboratories

First, appellant argues that the transition phrase "consisting essentially of" in the claims cannot be interpreted as being open to any unlisted ingredient, and the claims do not read on polynucleotides having sequence of inaccessible region of cellular chromatin (pages 12-13). Appellant cites MPEP 2111.03, which is copied from the brief on pages 12-13 as follows:

> *The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. ... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."*

Appellant's argument is not found persuasive for the following reasons:

With regard to interpreting the transition phrase "consisting essentially of," the Office's policy as set forth in foot note number 29 of the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement" (Federal Register/Vol. 66, No.4, Friday, January 5, 2001), which includes what appellant cited from the MPEP as shown above but is more extensive, and is copied below:

> *''By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format.'' PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353–54 (Fed. Cir. 1998). For the purposes of searching for and*

applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895–96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Firstly, while Appellant argues in the brief that the basic and novel characteristics of the claimed invention are isolating sequences of accessible regions of cellular chromatin (page 13), there is no clear indication in the specification or claims that these actually are the basic and novel characteristics of the invention. Further, appellant does not define the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regards as constituting a material change in the basic and novel characteristics of the invention. In other words, no indication of what should be included and excluded for the phrase "consisting essentially of." Thus, the term "consisting essentially of" is construed as equivalent to "comprising," and is open to any unlisted components. The invention of claim 66 is thus directed to a polynucleotide that is a member of a library having a vector and an insert, the insert comprising sequence of accessible regions. The claim does not exclude the presence of sequence

of inaccessible regions in addition to sequence of accessible regions in the same insert. Since the libraries disclosed by Clontech inherently comprise clones with insert that comprises both sequence of the accessible region and sequence of the inaccessible region, the Clontech libraries anticipate the claimed products.

Secondly, assuming arguendo that the specification or claims did indeed clearly indicate that the basic and novel characteristics of the claimed invention are isolating sequences from accessible regions of cellular chromatin, and appellant did indeed define the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention, the phrase "consisting essentially of" could still include other components, such as sequence of inaccessible regions, because they would not materially change the basic and novel properties of the invention. While the insert of the Clontech libraries contains both nucleotide sequence of the accessible region and sequence of the inaccessible region in a same insert, the presence of sequence of inaccessible region in the insert does not affect the basic and novel characteristics of the invention, i.e. isolating sequences of accessible region, because such sequence from accessible regions has been isolated from the genome and it is now present in the isolated insert of a clone.

Thirdly, the notion that "consisting essentially of" in claim 66 is open to other unlisted components is consistent with step (d) of the method used to produce the claimed polynucleotide, which step explicitly recites "selectively cloning polynucleotide fragments comprising one end generated by probe cleavage." This clearly indicates that what is produced is a clone having a fragment or insert that "comprises" one end generated by probe cleavage, i.e.

sequence from the accessible region, without excluding other sequences, such as sequence from the inaccessible region, due to the use of the word "comprising."

Therefore, the libraries disclosed by Clontech catalog anticipate the claimed polynucleotide and libraries comprising same.

Appellant then asserts that it is an error to assert that Clontech catalog discloses, expressly or inherently, each and every element of the pending claims because it does not describe contacting cellular chromatin with a probe and deproteinizing the cleaved cellular chromatin (brief, page 13, "(b) Clontech ..." through page 14).

This is not found persuasive because as set forth in the final rejection, the court in *In re Thorpe 777 F.2d 695, 698, 227 USPQ 964,966 (Fed. Cir. 1985)* held that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." For reasons set forth earlier, the libraries and clones contained therein disclosed by Clontech read on the product in the instant product-by-process claims. Consequently, whether or not the process of producing the libraries by Clontech catalog is the same as that used to produce the claimed product is irrelevant and does not affect the validity of Clontech catalog being used as a prior art reference.

Appellant further argues that Clontech catalog does not inherently anticipate the claims on appeal because the libraries of Clontech comprise fragments that include both accessible region and inaccessible region (brief, page 14, last paragraph, and page 15). This is also deemed unpersuasive. Indeed, as clearly admitted by the appellant in this very argument, Clontech's libraries do indeed comprise fragment that includes both sequence of accessible region and sequence of inaccessible region in the same clone or insert. For reasons set forth earlier, the phrase "consisting essentially of" in the claims allows presence of unlisted components. it is precisely clones of the libraries containing these fragments or inserts disclosed in the Clontech catalog that anticipate the claimed polynucleotides and libraries comprising them.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the reasons set forth hereinabove, it is respectfully submitted that the rejection should be sustained.

Respectfully submitted,

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